

REMARKS

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. 1.98(d), if the IDS submitted in the parent application of a Continuation-In-Part application complies with 37 C.F.R. 1.98 (a) to (c), copies of the patents, publications, pending U.S. applications, or other information submitted in the parent application need not be resubmitted in the Continuation-In-Part application. *See* MPEP §609. Applicants filed an IDS on September 30, 2004. In accordance with 37 C.F.R. 1.98(d), copies of references previously cited and/or submitted in prior related applications (i.e., Application No. 10/120,800, filed April 11, 2002; Application No. 10/135,316, filed April 29, 2002; Application No. 10/135,626, April 29, 2002) were not resubmitted for the pending application. However, copies of references, not previously cited and/or submitted, were submitted on September 30, 2004 for the pending application.

Nevertheless, for the sake of expediting prosecution of the pending application, Applicants submit herewith a copy of patents, publications, and pending U.S. applications, cited in the IDS.

CLAIMS

Claims 1-6, 8-15, 18-24, 26, 27 and 29-35 are currently pending in the application. Claims 13, 14, 32 and 33 have been withdrawn from consideration. In the Non-Final Office Action of March 31, 2006, the Examiner rejects pending claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 on anticipation grounds. Additionally, the Examiner objects to claim 2 for an informality.

Claim 2 has been amended to correct for the informality. The rejections to claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 are traversed. Applicants respond to the anticipation rejection as subsequently recited herein, and respectfully request

reconsideration and further examination of the present application under 37 C.F.R. §1.112.

A. Applicants overcome the Examiner's objection by amending claim 2.

The Examiner objects to claim 2 for purportedly inaccurately describing the invention. Claim 2 recited, in part, "one point of contact is positioned proximate either a proximal end or distal end of the microporous metal thin film covering..." According to the Examiner, "it is not possible for a point of contact to be more proximal than the proximal end of the stent." (See First Paragraph, Page 3 of the Office Action dated March 31, 2006.)

In view of the Examiner's remarks, Applicants amend claim 2 to now recite, in part, "wherein the at least one affixation member is positioned near either a proximal end or distal end of the microporous metal thin film covering..." Applicants submit that the amendment of claim 2 overcomes the Examiner's objection and thus respectfully request that the objection be withdrawn.

B. Applicants traverse the Examiner's rejection of pending claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 as being anticipated by EP 0 759 730 to Burmeister et al.

Applicants have thoroughly considered the Examiner's remarks concerning the patentability of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 and have meticulously read EP 0 759 730 to Burmeister, et al. (hereinafter referred to as "*Burmeister*"). For this 35 U.S.C. §102(b) rejection to be proper, each and every element of the claims must be disclosed in as great detail by the reference as claimed in the claims. See MPEP §2131; see also *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (holding that "[t]he *identical* invention must be shown in as complete detail as is contained in the ... claim." [Emphasis added]); see also *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (stating that anticipation

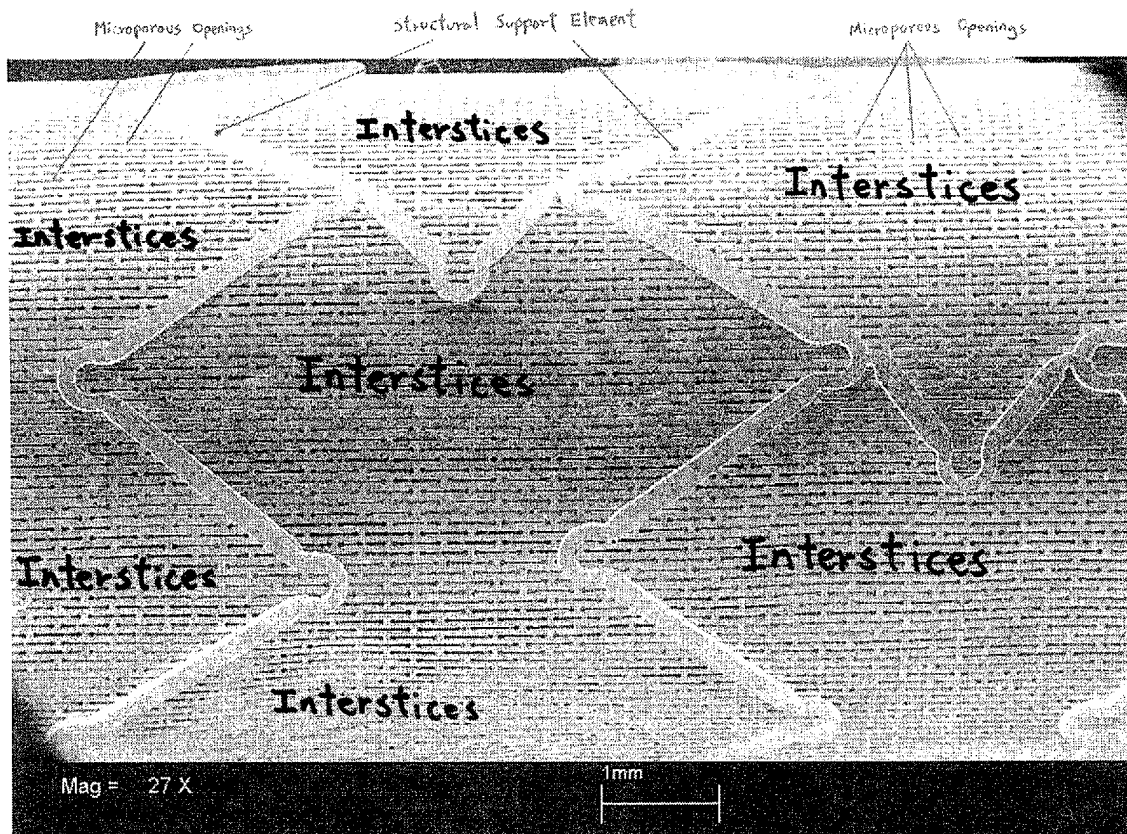
requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”). Additionally, while an identity of terminology is not required, the elements must nonetheless be arranged as required by the claim. *See In re Bond*, 910 F.2d 831, 832-833 (Fed. Cir. 1990) (holding that anticipation can not be established by mere equivalents).

Applicants respectfully traverse this anticipation rejection because *Burmeister* does not teach or suggest a microporous metal thin film. To the Applicants’ best understanding, the Examiner bases the anticipation rejection on *Burmeister*’s teaching of a two-layer stent (as shown in Figure 3 and described in Paragraphs 29-36), in conjunction with *Burmeister*’s teaching of a stent shaped with a pattern of elongated slots (as shown in Figures 11a and 11b). In other words, the Examiner appears to argue that an expandable configuration with elongated slots, as shown in *Burmeister* Figures 11 and 11b, could have been incorporated into *Burmeister*’s stent embodiment of Figure 3, thereby resulting in a stent comprised of two layers, with each layer retaining the stent structure of expandable configurations of Figures 11a and 11b.

Applicants submit that the *Burmeister* stent’s elongated slots (as shown in Figures 11a and 11b) are not comparable to the microporous openings formed onto the Applicants’ metal thin film because the *Burmeister* stent’s elongated slots are too large to be characterized as “microporous.” The “microporous” attribute that is unique and intrinsic to Applicants’ metal thin film is a feature of the Applicants’ invention which patentably distinguishes Applicants’ invention from that of *Burmeister*. With reference to the online dictionary <www.dictionary.com>, the term “microporous” is defined: “characterized by very small pores or channels with diameters in the micrometer or nanometer range.” This definition is consistent with what the term “microporous” means to those skilled in the stent arts. While the Examiner may argue that the *Burmeister* stent’s elongated slots are comparable to Applicants’ microporous openings, this is not the case; nowhere in *Burmeister* is there a reference to the size of the open spaces (elongated slots) intermediate two structural members of a stent. Without a specific

reference to size, the elongated slots as shown in Figures 11a and 11b *can not* be presumed to retain a microporous-like size -- let alone enable one skilled in the art to practice the invention in such a manner -- and thus must be considered in light of what is known to one of ordinary skill in the stent arts. In fact, to Applicants' best understanding of the stent arts, the open spaces (elongated slots) intermediate two structural members of a stent as taught by *Burmeister*, would not be interpreted by those skilled in the art to have microporous-sized dimensions. Simply put, the artisan understands that stent interstices are too large to be microporous.

To further clarify the distinction between interstices on a stent and microporous openings on a graft, Applicants refer to a micrograph of a stent with a graft covering, designated as Exhibit A in the Declaration of Mr. Dan Sims. The size differences between interstices on a stent and microporous openings on a graft are immense, as evidenced by the micrograph. Exhibit A illustrates a metal graft (i.e., metal thin film covering) overlying a conventional stent (i.e. structural support element). As shown in Exhibit A, whereas interstices on a conventional stent are sized in millimeter dimensions, microporous openings on a graft covering are typically sized in micrometer dimensions. Thus, it is abundantly clear to one skilled in the art that microporous openings on a graft are dimensionally of a much smaller scale than interstices on a stent.



The microporous-size dimensions of the openings on the metal thin film covering represent an important feature of Applicants' invention. As known to those skilled in the art and as discussed in the specification (paragraph 5) of the pending application, even after the implantation of an endoluminal stent, restenosis often recurs. This post-stenting restenosis is due, in large part, to the non-regrowth of the endothelial layer over the stent and the incidence of smooth muscle cell-related neointimal growth on the luminal surfaces of the stent. Injury to the endothelium (the natural nonthrombogenic lining of the arterial lumen) from stent placement is a significant factor contributing to restenosis at the situs of a stent. Endothelial loss exposes thrombogenic arterial wall proteins, which initiates platelet deposition and activation of the coagulation cascade, which results in thrombus formation, ranging from partial covering of the luminal surface of the stent to an occlusive thrombus.

As disclosed in the specification (paragraph 14) of the pending application, Applicants' microporous metal thin film covering (sometimes also referred to as a graft) overcomes the aforementioned problems faced by endoluminal stent use. Applicants' microporous metal film facilitates endothelialization of a stent by promoting cellular migration into microporous openings, while severely limiting (if not completely occluding) blood fluid flow therethrough. By facilitating the endothelialization of the stent, the incidence of restenosis is greatly reduced.

With specific regard to claims 1-6, 8-12, and 15, Applicants submit that *Burmeister* is devoid of any teaching, expressed or implied, of "an affixation member," as recited in claim 1. Similarly, *Burmeister* does not teach of "at least one projection extending longitudinally from a terminal cylindrical element," as recited in claim 29. Applicants kindly welcome the Examiner to specifically point out where in *Burmeister*, he sees a reference to an affixation member/projection. Unless the Examiner can show a specific reference in *Burmeister* to an affixation member or a projection, the Examiner's anticipation rejection of claims 4, 5, 8, 23, 29-31 and 34-35 is improper.

To conclude, because *Burmeister* fails to teach of a microporous metal thin film, let alone a microporous metal thin film covering a scaffold, the Examiner's anticipation rejection of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 is improper. Moreover, claims 1-6, 8-12, 15, 29-31, and 34-35 are further distinguished from *Burmeister's* invention by featuring an affixation member/projection that is not disclosed in *Burmeister*. Accordingly, Applicants kindly request that the Examiner withdraw the anticipation rejection.

Summary

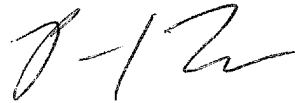
The Examiner's rejections of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34 and 35 have been obviated by the above remarks. In addition, the informality that formed the basis for the Examiner's to claim 2 has been corrected. Accordingly, Applicants submit that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited.

Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

This Paper is being concurrently filed with an Amendment Transmittal, which includes a fee calculation sheet and any applicable requests for Extension of Time. Other than those stated in the Amendment Transmittal, no additional fees are believed necessitated by the filing of this Paper. Should any such additional fees be required, the Director is hereby authorized to deduct them from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner believe that there are any outstanding matters capable of resolution by a telephone interview, the Examiner is encouraged to telephone the undersigned attorney of record.

Respectfully submitted

A handwritten signature in black ink, appearing to read 'P. Lee', with a stylized flourish at the end.

Paul J. Lee
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